Atty Dkt No. 1950-0001 Client No. CIT-3413

Serial No.: 10/091,372 Amendment dated September 24.

Amendment dated September 24, 2004 Reply to Office Action of March 25, 2004

Remarks

In accordance with 37 CFR § 1.111, entry of the foregoing amendments is respectfully requested.

In the Office Action under reply, the following rejections have been entered:

- 1) Claims 1-17 stand rejected under 35 U.S.C. 112, first and second paragraphs, as failing to adequately set forth critical elements of the invention;
- 2) Claims 1, 2, 5 and 11-17 stand rejected under 35 U.S.C. 102(b), as being anticipated by Ikariya et al. (U.S. Patent No. 6,184,381);
- 3) Claims 1-9 and 11-13 stand rejected under 35 U.S.C. 102(b), as being anticipated by Hosokawa et al. (J. Am. Chem. Soc. article);
- 4) Claims 1, 2, 5, 6 and 11-17 stand rejected under 35 U.S.C. 103(a), as being obvious over Ikariya et al.;
- 5) Claims 1-9 and 11-13 stand rejected under 35 U.S.C. 103(a), as being obvious over Hosokawa et al.; and
- 6) Claims 1, 2 and 5-17 stand rejected under 35 U.S.C. 103(a), as being obvious over Guram et al. (U.S. Patent No. 6,350,916).

Applicants respectfully traverse these rejections based on the foregoing amendments and/or the remarks that follow.

The Amendments:

By the foregoing amendments, claim 1 has been amended to include the recitation that the "chiral ligand comprises at least one chiral atom and two or more tertiary amines that are separated by two or more linking atoms". Support for this language may be found in the specification at, e.g., page 6, paragraph [00017], and in the original claims, e.g., in claim 25. Claims 16 and 17 have been amended to correct the reference to the claimed method rather than an organic compound.

New claims 43-47 are added as directed to the claims under consideration in which features associated with the chiral ligand are claimed. Support for these claims is present in the specification and the original claims, e.g., claims 30-32, 37 and 38.

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Accordingly, no new matter has been entered by the foregoing amendments.

Status of the Claims:

Claims 1-47 remain in the application, as amended. Claims 1-17, as amended, remain under consideration with claims 18-42 withdrawn from consideration as directed to a nonelected invention and species. New claims 43-47 are added as directed to the claims under consideration in which certain features associated with the chiral ligand are claimed.

Rejections under 35 U.S.C. §112, first and second paragraphs

Claims 1-17 stand rejected under 35 U.S.C. §112, first and second paragraph, as failing to set forth critical elements of the claimed invention. Applicants respectfully traverse this rejection for at least the following reasons.

In the Office Action, it is asserted that there is "not an adequate indication of the reactants, products, reagents and reaction conditions contemplated," that the "specification acknowledges that some of these elements are in fact critical which is not pointed out in the claims," and that "not all metal sources or chiral ligands embraced by the claims would be suitable." In reference to the information provided in Table 1, the Examiner has noted that only certain chiral ligands provide an enantiomeric excess. It is further noted that applicants have stated at page 22 that the "palladium source is critical."

Applicants respectfully disagree that the information noted in the Office Action adequately supports a conclusion that critical elements of the invention are not claimed.

At the outset, applicants note that the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). As is further stated in the MPEP §2164.04, "[a] specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling

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support." Further, as stated by the court in *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971), "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement."

In the present case, applicants have provided both a general disclosure of the reactants, reaction conditions and procedures as well as the results and products produced. Numerous examples have also been provided. As such, applicants respectfully submit that the skilled artisan has been provided with an "adequate indication of the reactants, products, reagents and reaction conditions contemplated" as suggested in the Office Action and that the claimed invention is properly enabled.

While it is true that the specification makes use of the word "critical" in reference to the "nature of the palladium source" (page 22 in reference to Table 2), applicants respectfully note that this choice of wording should not be taken literally. Instead, the information meant to be conveyed is more reasonably seen to be intended to impart an understanding to the skilled artisan that the resolution of 1-phenylethanol depends on the palladium source, i.e., that the Pd source is a factor having an influence on the enantiomeric excess and selectivity. In this sense, the word "critical" should not be understood to imply that some "critical" aspect of the invention has not been claimed.

Applicants further note, in accordance with MPEP §2164.08(c), "an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality."

In the present case, applicants submit that the description in the specification concerning the nature of the palladium source as being "critical" does not provide support for a conclusion that a specific palladium source should be claimed in order for the invention to function as intended. In addition, the specification does clearly provide broad language omitting the allegedly critical feature such that the criticality referred to cannot be presumed.

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As for the statement in the Office Action that "not all metal sources or chiral ligands embraced by the claims would be suitable," applicants respectfully submit that there is no basis to support such a conclusion. In particular, with regard to the "metal sources," the information provided in Tables 1 and 2 for palladium sources indicates that, while there is some variation in the enantiomeric excess and the selectivity, there nonetheless is an excess produced and an increased selectivity for each of the Pd sources listed. From this information, the skilled artisan would have no apparent reason to suspect that other metal compositions within the scope of the claims are not adequately enabled.

With regard to the ligands of Table 1 (page 22), applicants further note that merely because the ligands presented in this table show a variation in enantiomeric excess does not mean that the invention is not adequately enabled for the skilled artisan. In particular, the skilled artisan would still, without undue experimentation, be able to determine which chiral ligands may be used within the scope of the invention. While some experimentation may be necessary to determine the proper combination of a chiral ligand and metal composition, given the entirety of applicants' disclosure, including the examples, such experimentation would not be undue.

With regard to the additional statement set forth in the Office Action, i.e., that the specification does not adequately teach how to make and use the invention, or how to make such processes operable, applicants respectfully submit that the specification does in fact provide adequate support and disclosure for the skilled artisan to make and use the invention. As noted above, while some catalysts or chiral ligands may provide differing results, as with most any catalytic reaction, this is not a sufficient reason to conclude that the claims are not properly enabled. Instead, given the specificity of applicants' disclosure, including the examples provided by applicants, as well as the knowledge of the skilled artisan concerning the prior art, applicants' claimed invention could be utilized without undue experimentation.

For at least the foregoing reasons, applicants respectfully submit that the specification and claims are properly enabled and clear within the meaning of first and second paragraphs of §112. Accordingly, withdrawal of the §112, first and second paragraph rejections is requested.

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Rejections under 35 U.S.C. §102(b) and §103(a) over Ikariya et al.

Claims 1, 2, 5 and 11-17 stand rejected under 35 U.S.C. 102(b), as being anticipated by Ikariya et al. (U.S. Patent No. 6,184,381) and claims 1, 2, 5, 6 and 11-17 stand rejected under 35 U.S.C. 103(a), as being obvious over Ikariya et al. Applicants traverse these rejections for at least the following reasons.

In the Office Action, it is asserted that examples 79-93 of Ikariya et al. anticipate claims 1, 2, 5 and 11-17, and that claims 1, 2, 5, 6 and 11-17 are obvious due to the disclosure of other process parameters and/or "analogous reactants." Applicants respectfully disagree that the claims are properly rejected under either §102(b) or §103(a) based on this reference.

As set forth in claim 1, applicants' method includes contacting an organic compound with an oxidizing agent and a catalyst comprising a metal composition and a chiral ligand and producing an oxidized organic compound and a single enantiomer of the organic compound. By comparison, examples 79-93 of Ikariya et al. relate to the preparation of secondary alcohols using ruthenium-diamine complexes; e.g., example 79 concerns the synthesis of (R)-1-indanol using a ruthenium-diamine catalyst. However, in contrast to applicants' claims. Ikariya et al. does not disclose the use of an oxidizing agent in conjunction with a catalyst comprising a metal composition and a chiral ligand.

Applicants further note that Ikariya et al. refers to the use of hydrogen donating compounds, e.g., at column 4, lines 17-30, column 10, lines 2-13, and column 14, line 40 et seq. However, the particular types of compounds meant in this context include, e.g., alcohol compounds, formic acid and salts thereof, unsaturated hydrocarbon and heterocyclic compounds, hydroquinone or phosphorus acid or the like (column 10, lines 6-13), rather than oxidizing agents.

In accordance with MPEP §2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

In the present case, Ikariya et al. does not disclose each and every element of the claims, either explicitly by reference to the addition of oxidizing agents, or by the use of Serial No.: 10/091,372 Amendment dated September 24, 2004 Reply to Office Action of March 25, 2004

oxidizing agent compounds in conjunction with a catalyst comprising a metal composition and a chiral ligand. As such, applicants' claims are neither anticipated by, nor obvious over, this reference.

Further, to the extent the Examiner may consider that the use of an oxidizing agent is somehow inherent in Ikariya et al.'s process, it should be kept in mind that inherency requires more than simply a "possibility." Instead, it must be shown that applicants' claimed feature is necessarily part of Ikariya et al.'s process. (see, e.g., MPEP §2112IV, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993): "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic"; *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981): "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities"; and *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999): "The mere fact that a certain thing may result from a given set of circumstances is not sufficient").

In the present case, there is nothing that supports a conclusion that Ikariya et al. necessarily includes an oxidizing agent in the process disclosed therein. As such, Ikariya et al. cannot properly be considered to inherently include such a feature.

Applicants further submit that the statements concerning "analogous reactants" in the Office Action and the use of "other process parameters" are not pertinent to the failure of Ikariya et al. to disclose or suggest the use of oxidizing agents in conjunction with a catalyst comprising a metal composition and a chiral ligand. Applicants' claims are therefore also not properly rejected for obviousness on these grounds.

For at least the foregoing reasons, the claims are patentable over Ikariya et al. Accordingly, withdrawal of the rejections under 35 U.S.C. §102(b) and §103(a) is requested.

Rejections under 35 U.S.C. §102(b) and §103(a) over Hosokawa et al.

Claims 1-9 and 11-13 stand rejected under 35 U.S.C. 102(b), as being anticipated by Hosokawa et al. (J. Am. Chem. Soc. article) and claims 1-9 and 11-13 stand rejected

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under 35 U.S.C. 103(a), as being obvious over Hosokawa et al. Applicants traverse these rejections for at least the following reasons.

In the Office Action, it is asserted that the "examples and tables" of Hosokawa et al. anticipate claims 1-9 and 11-13, and that claims 1-9 and 11-13 are obvious due to the disclosure of other process parameters and/or "analogous reactants." Applicants respectfully disagree that the claims are properly rejected under either §102(b) or §103(a) based on this reference.

As set forth in claim 1, applicants' method includes contacting an organic compound with an oxidizing agent and a catalyst comprising a metal composition and a <u>chiral ligand</u> and producing an oxidized organic compound and a single enantiomer of the organic compound. As claimed, the <u>chiral ligand</u> comprises at least one chiral atom and two or more tertiary amines that are separated by two or more linking atoms. By comparison, Hosokawa et al. relates to a study of Wacker-type oxidation, specifically the asymmetric oxidative cyclization of 2-allyphenol with a palladium(II) catalyst in the presence of copper acetate and molecular oxygen. As further described in the results section at pages 2318-2319, the palladium(II) catalyst may include a ligand such as pinanyl (structure 1, page 1219), (-)carvone, (+)-calciferol, and N,N-dimethyl-(-)-α-phenylethylamine.

In contrast to applicants' claims, Hosokawa et al. does not disclose or suggest chiral ligands comprising at least one chiral atom and two or more tertiary amines that are separated by two or more linking atoms. Hosokawa et al. therefore does not disclose each and every element of the claims, either explicitly by reference to applicants' claimed chiral ligand, or by the use of such ligands in conjunction with a catalyst according to applicant's claims. As such, applicants' claims are neither anticipated by, nor obvious over, this reference.

Moreover, there is no motivation to modify Hosokawa et al. through the use of a chiral ligand according to applicants' claims.

For at least the foregoing reasons, the claims are patentable over Hosokawa et al. Accordingly, withdrawal of the rejections under 35 U.S.C. §102(b) and §103(a) is requested.

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Rejections under 35 U.S.C. §102(b) and §103(a) over Guram et al.

Claims 1, 2 and 5-17 stand rejected under 35 U.S.C. 103(a), as being obvious over Guram et al. (U.S. Patent No. 6,350,916). Applicants traverse this rejection for at least the following reasons.

In the Office Action, it is asserted that Guram et al. "generically teaches" applicants' claimed method, the disclosure in the paragraph bridging columns 15-16 and in claims 18 et seq. being cited by the Examiner. It is further stated that any variations in the claims compared with Guram et al.'s process are obvious or within the level of skill in the art due to the disclosure of process parameters and/or "analogous reactants." Applicants respectfully disagree that the claims are properly rejected under §103(a) based on this reference.

As set forth in claim 1, applicants' method includes contacting an organic compound with an oxidizing agent and a catalyst comprising a metal composition and a <u>chiral ligand</u> and producing an oxidized organic compound and a single enantiomer of the organic compound. As claimed, the <u>chiral ligand</u> comprises at least one chiral atom and two or more tertiary amines that are separated by two or more linking atoms. By comparison, Guram et al. describes the use of metal-ligand compositions or complexes in which suitable ligands have the general formulas: PR₃, NR₃, SR₂, OR₂, or :CR₂, (column 2, line 51 et seq.; column 10, line 28 et seq.). As may be further noted from the claims of Guram et al., the claimed ligand corresponds to one of the general formulas: PR₃, NR₃, OR₂, or :CR₂, (see claims 1, 13, 14, and 18).

In contrast to applicants' claims, Guram et al. does not disclose or suggest the use of chiral ligands comprising at least one chiral atom and two or more tertiary amines that are separated by two or more linking atoms. Guram et al. therefore does not disclose each and every element of the claims, either explicitly by reference to applicants' claimed chiral ligand, or by the use of such ligands in conjunction with a catalyst according to applicant's claims. As such, applicants' claims are not obvious over this reference.

Moreover, there is no motivation to modify Guram et al. through the use of a chiral ligand according to applicants' claims.

For at least the foregoing reasons, the claims are patentable over Guram et al. Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) is requested.

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Conclusion

Accordingly, applicants respectfully submit that the pending claims are novel and nonobvious over the art, and are in condition for allowance. A prompt notice to that effect would be appreciated.

If the Examiner has any questions concerning this amendment, or the accompanying remarks, a telephone call to the undersigned would be appreciated.

Respectfully submitted,

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